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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91194218
Party	Defendant Meridian Bioscience, Inc.
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL APPEAL BOARD

ILLUMINA, INC.,	)	Opposition No. 91194218 (parent)
	)	Ser. No. 77/768176
Opposer/Petitioner,	)	
	)	Opposition No. 91194219
-v-	)	Ser. No. 77/775316
	)	
MERIDIAN BIOSCIENCE, INC.,	)	Cancellation No. 92053479
	)	Reg. No. 3887164
Applicant/Registrant.	)	
	)	Cancellation No. 92053482
	)	Reg. No. 3868081
	)	

DECLARATION OF VECHESLAV A. ELAGIN, PH.D., MBA

I, Vecheslav (Slava) A. Elagin, hereby state and declare as follows:

1. My name is Vecheslav A. Elagin, I am over eighteen (18) years of age, and I have personal knowledge of the facts stated in this Declaration.

My Background, Education and Experience

2. In 1988, I earned a Bachelors of Science degree in Applied Physics and Mathematics from the Moscow Institute of Physics and Technology in Moscow, Russia. In 1990, I earned a Masters degree in Genetics from the Vavilov Institute of General Genetics in Moscow, Russia. In 1992, I earned my doctorate in Molecular Genetics from the Engelhard Institute of Molecular Biology in Moscow, Russia. And in 2009, I earned an executive MBA from the University of Wisconsin in Madison, Wisconsin. I have worked as an academic in the field of molecular genetics, including as a Staff Scientist and Principal Investigator at the Institute of Gene Biology in Moscow, Russia from 1992 to 1996, and as a Research Assistant Professor at the University of Notre Dame in Indiana from 1996 to 2000.

3. I am currently employed by Meridian Bioscience, Inc. ("Meridian") as Executive Vice President, Research and Development. I have worked for Meridian since 2009, when I started as Vice President, Research and Development. In 2011, I was promoted to Senior Vice

President, Research and Development, and in 2012 I was promoted to my current position. I currently report directly to Meridian's CEO and am responsible for corporate-wide leadership of Meridian's research and development.

4. Among other duties, I oversee Meridian's research and innovation projects, as well as development of in-vitro diagnostic products (often referred to as "IVD" products), including strategies, policies, FDA compliance as it relates to new product development, and design control, clinical trials, valuation and protection of intellectual property, etc. I have direct involvement in Meridian's development of molecular diagnostic products and assessment of other companies' products, services, and intellectual property. Through my work, I have gained substantial personal knowledge of both Meridian's and other companies' products.

5. From 2006 to 2008, I was employed by EraGen Biosciences as a Vice President, Research and Development. EraGen Biosciences was acquired by Luminex Inc. in the third quarter of 2011. EraGen developed and commercialized molecular diagnostic products and drug discovery molecular tests. At EraGen, I was responsible for the full scope of research and development within the company, including product development, validation and verification testing, commercialization of Eragen's products and the development and protection of the company's intellectual property.

6. Prior to my work at EraGen, I worked from 2004 to 2006 as a Vice President, Research and Development, at Third Wave Technologies (which was acquired by Hologic Inc. in 2008). Third Wave operated in two distinct segments: Life Science (or research applications) and Molecular Diagnostics (or IVD products). My role involved guiding research, product support, quality control, regulatory submissions, and other technical operations.

7. In 2000 to 2003, I worked for Visible Genetics (which was acquired by Bayer Diagnostics in 2002). My title was Senior Scientist/Manager, Research and Development. I managed a group of scientists in the research and development department, developing new IVD products. I also served as a Manager for Clinical Laboratory Operations at Visible

Genetics, which involved managing clinical laboratory operations carried out by the company in accordance with CLIA[1] and FDA standards.

8. Through over a decade and a half of personal experience in the clinical diagnostics industry, including in research, product development, regulatory work, and management, I have come to know the industry very well. I have personal knowledge of the types of clinical diagnostics products that have been available in the market historically, their scientific bases, their functions, and the regulations that apply to them.

The Goods And Services Recitations in Meridian's and Illumina's Trademark Applications Describe Different Products and Services Marketed to Different Consumers.

9. I have reviewed the goods and services recitations in Meridian's registrations and applications for its ILLUMIGENE mark, Registration No. 3868081; ILLUMIGENE design & mark, Registration No. 3887164; ILLUMIPRO mark, Serial No. 77/768176, and ILLUMIPRO-10 mark, Serial No. 77/775316. I have also reviewed the goods and services recitations in the registrations owned by Illumina for its ILLUMINA mark, specifically Registration Nos. 2471539, 2632507, and 2756703. The recitations of goods and services in Meridian's and Illumina's applications and registrations are technically complex, and the nature of the products and services described therein cannot be understood by someone who does not possess the requisite scientific background. My education and experience, described above, allow me to interpret the scientific and technological terms and to understand the concepts being described.

10. Moreover, to someone with skill in these scientific fields, Illumina's recitations of products and services are extremely vague, and understanding their meaning requires knowledge about Illumina's actual activity in the marketplace and product offerings as context. I will discuss this in more detail below.

[1] "CLIA" stands for the Clinical Laboratory Improvement Amendments issued by the Centers for Medicare & Medicaid Services, which regulate all laboratory testing, except research, performed on humans in the United States.

The Recitations Of Goods And Services In Meridian's Applications

11. Meridian's recitation of goods is the same for its ILLUMIGENE and its ILLUMIGENE MOLECULAR SIMPLIFIED & design registrations, specifically: "Diagnostic kits consisting of molecular assays for use in disease testing and treatment of gastrointestinal, viral, urinary, respiratory and infectious diseases." One with applicable scientific education and/or experience would understand this recitation to describe IVD products because the goods described are "*diagnostic kits*" that are to be used in "testing *and treatment.*" Moreover, the term "molecular assays" in this context would be interpreted by one with skill in the field to mean an amplification/detection test for microbial, viral, or other disease-causing agents.

12. Meridian's recitation of goods is the same for its ILLUMIPRO and ILLUMIPRO-10 applications, specifically: "Diagnostic machine, namely, a stand alone closed heater and turbidity meter to be used for the amplification and detection of a closed tube molecular assay." One with applicable scientific education and/or experience would understand this recitation to describe machines to read IVD products because it discusses a "*diagnostic machine*" used in "a closed tube molecular assay" for "amplification and detection." To one skilled in the field, these words mean that the tests being run are used for detection of disease in patients (as opposed to analysis for research). The "amplification and detection" in such an assay keys one with the requisite knowledge to know this.

The Contrasting Recitations Of Goods And Services In The ILLUMINA Applications

13. To someone with applicable scientific education and/or experience, Illumina's recitations of goods and services in its ILLUMINA trademark registrations provide a stark contrast to Meridian's recitations of goods, indicating that the goods and services at issue are in a different field of medical endeavor from Meridian's with different interested consumers.

14. The recitation of services for ILLUMINA, Registration No. 2471539, is "Developing, to the order and specification of others, biological and/or chemical sensing systems which use random array technology to identify inorganic and organic molecules,

compounds and substances." One of skill in the field would understand immediately that Illumina is describing the development of complex, custom made equipment "to the order and specification of others" and using "random array technology." He or she would recognize that nothing in Meridian's trademark registrations and applications refers to any good or service that would use "random array technology." The definition of "random array technology" is vague and requires additional explanation. My understanding is that the term "random" implies that a system has random access for a sample input, and "array" means microarray technology. In other words, it is a system that utilizes random access sample inputs and uses microarray technology for analysis of organic and inorganic compounds. "Microarray" means that a system can analyze several biological markers (proteins, DNA molecules, RNA molecules) from a single sample or multiple samples in a single format. This technology is completely different from the ILLUMIGENE technology which utilizes a single analyte amplification and detection by turbidimetry. Simply put, Meridian does not use microarray technology generally, nor does it specifically use microarray technology in the ILLUMIGENE and ILLUMIPRO products. Moreover, ILLUMINA-branded products are in a different field of endeavor with different consumers - consumers who are looking not for "ready-made" IVD tests and locked IVD software on readers of those tests, but rather for open-platform research equipment that customers can tweak – certainly RUO products, not IVD products. The "random array technology" described in this recitation implies such open-platform research equipment that is used by consumers separate and distinct from the ready-made "kits" identified in Meridian's ILLUMIGENE recitations.

15. There are two more ILLUMINA registrations, with three additional recitations of goods and services. The goods description found in Registration No. 2756703 reads: "Scientific equipment and instruments, namely scanners, hybridization stations and fluidics delivery and computer systems sold as a unit and cassettes containing molecular sensing optical fiber bundles for analyzing cells, proteins, nucleic acids and other molecules of 50 to

10,000 daltons, sequencing dna, genotype, gene expression profiling and high through-put screening." The services description found in Registration No. 2632507 reads: "Scientific and medical research, namely, analysis of cells, proteins, nucleic acids and other molecules of 50 to 10,000 daltons, sequencing dna, genotyping, gene expression profiling and high through-put screening."; and the goods description reads: "Chemicals, namely reagents for scientific or medical research use for analyzing cells, proteins, nucleic acids and other molecules of 50 to 10,000 daltons, sequencing dna, genotyping, gene expression profiling and high through-put screening."

16. All of these additional recitations tell one with education and experience in the field that the products being discussed are RUO, not IVD, products, and are not similar to the products described in Meridian's recitations. The first recitation describes types of equipment that are used in scientific research, and "cassettes" specifically including "molecular sensing optical fiber bundles." To someone with the applicable scientific knowledge, this type of "molecular sensing" using "optical fiber bundles" stands in a stark contrast to Meridian's "molecular assays" using "heat" and "turbidity." Illumina's recited products are scientific equipment and specifically for "analyzing" the biological material at issue in a multiplex scale by employing "optical fiber bundles" – that is, specifically identifying and characterizing it -- not amplification and detection of a single analyte with the "heat" and "turbidity" approach utilized by Meridian's goods. These different approaches, in and of themselves, imply different consumers who are using the respective goods for different purposes. The two types of tests have critically different functions and contexts, with different applications and consumers: those who would be interested in a single target detection in a closed system for human in vitro diagnostics testing (Meridian's ILLUMIGENE product) on the one hand versus those seeking to identify multiple analytes in a high throughput screening context (Illumina's "sequencing dna, genotyping, gene expression profiling and high through-put screening" products, for instance). For example, an individual using an Illumina product for "high through-put screening" is not attempting to identify

a single pathogen in a human sample. Rather, that individual is conducting research on a large scale attempting to identify a number of different genetic variations that might be present in a person's DNA.

17. Similarly, the recitations of goods and services in Registration No. 2632507 are quite clearly RUO products and services, when read by someone with applicable scientific education and/or experience. They are specifically limited to "research use" and "scientific and medical research." There is no "diagnostic" or "clinical" utility expressed in Registration No. 2632507 at all. Other than that, when read by someone with skill in the field, these recitations are extremely vague, such that one would need to know more about Illumina's actual activities to understand what particular products and services are implicated.

Illumina's Actual Activity In The Marketplace In 2000 To 2009 Helps Someone With The Requisite Scientific Knowledge To Understand Its Vague Recitations of Goods And Services

18. Considering Illumina's actual activity in the marketplace at the time of these applications and the first uses claimed in their registrations (2000-2003), and up through the 2008-2009 timeframe, one with the applicable scientific background would understand that these recitations describe the detailed study and characterization of human genetic material in scientific research. Again, the consumers interested in such goods and services are dramatically different from the consumers who are interested in clinical diagnostic tests to detect infectious disease – that is, Meridian's ILLUMIGENE products.

19. I have reviewed the deposition testimony of Karen Possemato, Illumina's current Chief of Staff, and it serves to confirm my understanding, discussed above, that Illumina's recitations of products and services are technically complex and vague. Ms. Possemato testified that she worked in marketing for Illumina from 2004 to 2013. In 2007 to 2010, she was director of corporate marketing, and from 2010 to August 2013, she was senior director of corporate marketing. She has a bachelors degree in biochemistry. (Possemato Deposition, at 9, 17-18)

20. When Ms. Possemato was asked about the language in the first filed recitation of goods and services for the ILLUMINA mark, quoted in paragraph 14 above, she testified that the description did not mean anything to her and she did not know if Illumina ever provided the recited services. (Possemato Deposition, at 54-55)

21. When Ms. Possemato was asked about the language of the three other recitations of goods and services in Illumina's two other registrations for the ILLUMINA mark, quoted in paragraph 15 above, she was not able to comment on "the '50 to 10,000 daltons thing," a phrase that appears in Registration Nos. 2632507 and 2756703. She was not sure what "reagents" were being referred to in the product recitation, but generally testified that Illumina's reagents are sold to be used on the technological platforms that Illumina provides. She testified that Illumina's recited services are "genotyping and sequencing services," in which human (including prenatal) genetic samples are sent away to Illumina's laboratories to be tested, and Illumina sends back a report, along with consultation over the phone and provision of data. She also testified that Illumina's recited scientific equipment and instruments are components and systems whose only use is to do microarray analysis, and that Illumina is "obsoleting" all of the recited equipment and instruments such that they "are not available today." (Possemato Deposition, at 55-69, 73). Ms. Possemato's statement about scientific equipment and instruments used to conduct microarray analysis fits very well with my understanding of Illumina's Registration No. 2471539 which describes a "random array technology" instrument that utilizes microarray technology.

22. Accordingly, although Ms. Possemato did not describe the limitation of "50 to 10,000 daltons" in each of three recitations, she could confirm, by comparing the recitations to Illumina's actual products, that the recitations described reagents sold for use on Illumina's platforms; specific human genetic services offered through laboratories in consultation with the professionals who ordered the services; and discontinued systems that Illumina previously sold to support microarray analysis.

23. After Ms. Possemato's testimony, and applying my scientific education and experience to what she said about Illumina's goods and services recitations, it is even more evident that the recitations found in the ILLUMINA registrations are very different from the recitations associated with Meridian's marks, and that they relate to a very different market of consumers.

24. All of the ILLUMINA goods and services recitations, in light of Ms. Possemato's testimony and my scientific understanding, specify that the goods and services will be used in scientific research, human genetic sequencing or genotyping, and specifically by using microarray assays. None of Meridian's recitations relate to products that would serve those uses. Meridian's recitations discuss FDA-cleared "diagnostic kits" and FDA- cleared diagnostic machines using a turbidity meter on a closed-tube molecular assay; someone with the applicable education and/or experience would read Meridian's recitations to have absolutely nothing to do with scientific research, human genetic sequencing or genotyping, or microarray assays.

25. The consumers of such FDA- cleared "diagnostic kits" and "diagnostic machines" (that is, the products in Meridian's product recitations) are not the same as consumers of scientific research, human genetic sequencing or genotyping, and equipment for microarray assays (that is, the products and services in the ILLUMINA recitations). The consumers of "diagnostic kits" and "diagnostic machines" are treating/clinical physicians looking for an inexpensive and quick way to confirm or deny the presence of a particular bacteria, fungus, or virus. That is, they are asking the question, "Does this patient have the disease X?" The consumers of scientific research, human genetic sequencing or genotyping, and equipment for microarray assays are answering very different kinds of questions, and ones that are much more open-ended. For example, they are asking the question, "Do these 100 patients that present with cancer have the same type of cancer that derives from the same specific genetic sequence or are multiple genetic sequences responsible for the same type of cancer?"

Illumina's and Meridian's Products Are Different And Serve Different Consumers' Needs.

26. The disparity between the goods and services recitations in Meridian's applications and the ILLUMINA mark applications is not a coincidence. Considering the state of the companies and marketplace at the relevant time, along with my applicable education and experience, it is clear the relevant consumers implied in the recitations are not remotely the same. It is not a coincidence – it is a logical consequence of the very significant differences between the companies and their products at the time the parties' respective trademarks were applied for and registered.

27. In 2008, Illumina's products had zero presence inside a Clinical Diagnostic or Microbiology Laboratory. For the purpose of clarification, the Diagnostic Laboratory is a laboratory that performs diagnostic tests (also referred to as "in vitro diagnostic" or "IVD tests") on samples taken from the human body, and used in a broad range of applications to aid the physician or caregiver in reaching decisions. In October of 2008, Meridian announced it was developing a next-generation, molecular test for *C. difficile* to supplement its existing portfolio of products directed to this market. Attached as Exhibit A is a copy of that press release, and the subsequent press release announcing FDA clearance for that product – the ILLUMIGENE product. In 2008 to 2009, Illumina's products and services were focused on research applications as "Research Use Only" ("RUO") products and were not cleared by the FDA for "In Vitro Diagnostic" use ("IVD"). These RUO products are used by academic laboratories, medical centers for research purposes, government research entities, large pharmaceutical companies who do substantial research, and research laboratories, *not* the clinical diagnostic laboratories. In general, Illumina operated in the research market segment, similar to other companies like Life Technologies, Luminex, and the Life Science Division of Roche. Clinical Diagnostic Laboratories use IVD products, and Illumina had no IVD products at the time.

28. In a small number of medical institutions, or in much larger and well-funded institutions, researchers in the research laboratory side do work that could be considered, in one

sense of the word, "diagnostic," but it is not through the use of IVD clinical diagnostic products such as Meridian's ILLUMIGENE products. Rather, in this small subset of laboratories, researchers create their own diagnostic assays from RUO parts and components or use RUO products to conduct medical research studies, such as biomarker discoveries for different human diseases (cancers, inherited diseases, etc). To develop these assays, such researchers may use Illumina's products, along with components from many other suppliers, but those researchers and the people working with them are not buying "ready-made" clinical diagnostic products – kits – such as Meridian's. They are buying life sciences components and then *building* in-house diagnostic assays themselves – these are called "Laboratory-Developed Tests" or "LDTs." These products are sometimes referred to as "home brews" because the individual laboratory creates them themselves from various components.

29. I have reviewed the deposition testimony of Illumina's employee Naomi O'Grady, who makes some relevant comments that I agree with on this particular topic. Ms. O'Grady, who works for Illumina in the field of marketing related to oncology, gave a statement in this case on behalf of Illumina. At her deposition, she acknowledged that when laboratories use Illumina's components or equipment to make LDTs for a diagnostic purpose, the output of the laboratory is a "test report" sent by the laboratory to the ordering physician with no involvement from Illumina. Illumina would not review the report, would have no control over the report's content, and would have no control over the report's branding. As Ms. O'Grady testified, "No, they would not control that branding." (O'Grady Deposition, at 92-94)

30. What Ms. O'Grady says about LDTs in this passage matches my knowledge of that market. And that is not just a coincidence – it is necessary due to the nature of the regulatory environment and the market. If a test is providing a diagnostic answer, it must either be cleared by the FDA or it must be conducted in a CLIA-certified laboratory. The CLIA-certified laboratory may use equipment and consumables that are labeled for RUO, but such use does not somehow convert those components into diagnostic kits – far from it. Rather, the diagnostic

product involved is the laboratory's own LDT which is built from non-IVD components, and the process of building the LDT and using the LDT must be carefully controlled under CLIA regulations. Otherwise, the individual pieces of equipment and consumables used with that equipment would need to be separately cleared by the FDA as IVD products. The only "diagnostic product or service" in this LDT environment, necessarily due to the regulations, is the test report from the laboratory, and it must be issued by the laboratory itself – not by the manufacturer of the components used to construct the LDT. That is why Illumina can have nothing to do with the test report – its components are not FDA-cleared as IVD products. The market is simply not the same for RUO life sciences components as it is for IVD clinical diagnostic tests.

31. One example of an RUO life science component Illumina sells is "DisplaceAce." (Illumina sells DisplaceAce because it acquired Epicentre Technologies Corporation, a research tool company that sells enzymes and other components for life science applications, in January of 2011). DisplaceAce is Epicentre's brand name for *Bacillus stearothermophilus* DNA Polymerase (Bst), an enzyme that has been known for more than 30 years. This enzyme is also available from other research tool companies that are selling RUO components – New England BioLabs for example. Meridian was using the "DisplaceAce" enzyme as part of its ILLUMIGENE IVD kit when the ILLUMIGENE product initially received its FDA clearance. In order to use "DisplaceAce" in that cleared product, Meridian applied strict manufacturing and quality control oversight of Epicentre, went through development of an extensive manufacturing validation process on its own, and then conducted clinical trial studies with over 1,000 human samples. When Illumina informed Meridian, post acquisition, that it would cut off Meridian's supply of DisplaceAce, Meridian easily replaced its source through another supplier of an equivalent recombinant Bst DNA Polymerase by re-validating manufacturing and quality control processes and conducting additional clinical trial with human samples to demonstrate substantial

equivalency of this enzyme. This level of quality, process, design, and manufacturing control exemplifies the differences between marketing an RUO versus an IVD product.

32. The differences in the RUO versus IVD markets is further emphasized by the testimony of Karen Possemato that during the time she was director of corporate marketing for Illumina (which includes the years 2008 to 2009), she did not consider Meridian to be a competitor. (Possemato Deposition, at 82-87) In fact, Ms. Possemato essentially testified that comparing Illumina's products to Meridian's products would be like comparing apples to oranges. (Possemato Deposition, at 82-89) Her explanatory testimony on this topic is somewhat complex technically, but I understand it due to my relevant education and experience, and can explain further.

33. In discussing another company, Luminex, Ms. Possemato testified that currently, she does not consider Luminex to be a competitor. She explained that the Luminex technology offers a level of multiplexing of 100 or 200, while the Illumina platforms offer a level of multiplexing on the level of 100,000. "Multiplexing" essentially refers to the number of analytes from the same sample that can be run by one machine at one time. Ms. Possemato testified that comparing the two companies' products would be comparing "apples and oranges" due to the drastic difference in their multiplexing capabilities, i.e., 100,000 on the one hand versus 100 or 200 on the other.

34. Meridian's ILLUMIGENE and ILLUMIPRO/ILLUMIPRO-10 are inexpensive kits and readers for kits that simply say whether a person has one particular infectious disease or not. It is therefore even more drastically different from Illumina's products – it has a multiplexing level of 1. Put differently, the ILLUMIGENE product has no multiplexing capability whatsoever. (Possemato Deposition, at 82-89)

35. Viewed in light of my education and experience, I agree with Ms. Possemato that Illumina's products are drastically different from Meridian's in this way, and consequently they are viewed very differently by customers. Indeed, if comparing the "level 100,000" to the "level

100" is akin to comparing "apples and oranges," then further comparing the "level 100,000" of Illumina's products to the "level 1" of Meridian's products would be akin to comparing "apples and bananas;" even more drastically different.

Even After the 2008-2009 Time Period, Illumina's Products and Meridian's Products Remained Very Distinct, With Very Different Consumers.

36. I understand that after the 2008-2009 time period, Illumina received FDA clearance for a few IVD products, namely the Veracode Genotyping Test for Factor V and Factor II using the BeadXPress system (the "Veracode Genotyping Test"). Later, in 2013, Illumina received FDA clearance for two cystic fibrosis gene sequencing assays called the MiSeqDx Cystic Fibrosis 139-Variant Assay, and the MiSeqDx Cystic Fibrosis Clinical Sequencing Assay. These products, too, are very different from Meridian's ILLUMIGENE products and the ILLUMIPRO readers.

37. The Veracode Genotyping Test and the BeadXPress system on which it ran have been discontinued by Illumina. During the short period of time when it was available, the test was based on nucleic acid amplification and solid-phase hybridization technology to detect single nucleotide polymorphisms (SNPs) that cause human inherited diseases (coagulation factors in that case), and it has nothing to do with infectious disease or microbiology laboratories. From a technical standpoint, users of the Veracode Genotyping Test were interested in identifying a human single nucleotide polymorphism (i.e. a genetic mutation thought to be responsible for a given disease state), not detection of infectious diseases through amplification in a closed tube molecular assay, as with ILLUMIGENE and ILLUMIPRO. The technology platforms are entirely separate, fundamentally different, and incompatible with one another. In essence, the Veracode technology was very similar to the xTAG technology that is developed and commercialized by Luminex Inc. and would have been marketed to the same consumer.

38. Meridian's ILLUMIGENE and ILLUMIPRO products are wholly unrelated to Illumina's Veracode Genotyping Test, and the two technologies cannot be used together or combined in any way. Illumina's BeadXPress instrument cannot be used with Meridian's ILLUMIGENE tests. Meridian's ILLUMIPRO machines cannot be used with Illumina's Veracode Genotyping Test or any of Illumina's other products. A lab technician who may be exposed to both companies' products (assuming this would occur), would be keenly aware of this incompatibility.

39. Because of the function and focus of the Veracode Genotyping Test, users of that test would work in Hematology or Human Genetics departments. This is in contrast to users of Meridian's ILLUMIGENE clinical diagnostics products, who would be in Infectious Disease, Virology, or Microbiology departments. Analyzing human genetics is a totally separate scientific field from detecting infectious diseases.

40. Illumina's only current IVD products are the MiSeqDx Cystic Fibrosis 139-Variant Assay and the MiSeqDx Cystic Fibrosis Clinical Sequencing Assay (the "MiSeqDx Cystic Fibrosis Assays." These assays are entirely separate and fundamentally different from Meridian's ILLUMIGENE products and its ILLUMIPRO readers and serve very different markets. The MiSeqDx Cystic Fibrosis Assays are based on a next-generation sequencing platform that allows users to perform simultaneous analysis of more than 100 genetic mutations in a single test. The consumer of such a product is analyzing what causes human inherited diseases (cystic fibrosis in this case), and it has nothing to do with the analysis that is conducted in infectious disease or microbiology laboratories where the technician is trying to perform a specific test quickly in order to identify what is making a patient sick so that he can be treated. From a technical standpoint, users of a MiSeqDx Cystic Fibrosis Assays are interested in identifying a set of human single nucleotide polymorphisms (i.e. genetic mutations thought to be responsible for a given disease state), not detection of infectious diseases through amplification in a closed tube molecular assay, as with ILLUMIGENE and ILLUMIPRO.

41. Meridian's ILLUMIGENE and ILLUMIPRO products are wholly unrelated to Illumina's MiSeqDx Cystic Fibrosis Assays, and the two technologies cannot be used together or combined in any way. The MiSeqDx Cystic Fibrosis Assays run on a MiSeq instrument cannot be used with Meridian's ILLUMIGENE tests. Meridian's ILLUMIPRO machines cannot be used with the MiSeqDx Cystic Fibrosis Assays or any of Illumina's other products. A lab technician who may be exposed to both companies' products (assuming this would occur), would be keenly aware of this incompatibility.

42. Because of the function and focus of the MiSeqDx Cystic Fibrosis Assays, users of that test would work in the Genetics Counseling or Human Genetics departments. This is in contrast to users of Meridian's ILLUMIGENE clinical diagnostics products, who would work in Infectious Diseases, Virology, or Microbiology departments. As stated above, analyzing human genetics is a totally separate field from detecting infectious diseases.

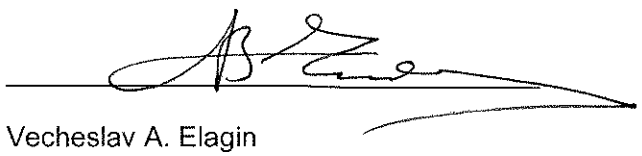
43. And in any event, Illumina's 510(k) clearances for the above-described products occurred between 2010 and 2013. In the 2008 to 2009 time period, an Illumina FDA-cleared product simply did not exist.

44. Even after those Illumina products were cleared by the FDA, the clinical diagnostic community did not consider Illumina or its products to be competitive with Meridian and its products. For example, attached as Exhibit B is a copy of a slide presentation given by Dr. Stephen Young, Professor in the Department of Pathology of the University of New Mexico. This presentation was given to prospective consumers at a Meridian-sponsored workshop at the Association for Molecular Pathology Annual Meeting which ran from 17-20 November 2010 in San Jose, California. I attended this presentation and introduced Dr. Young. In this presentation, Dr. Young discussed the various solutions available to someone performing molecular assays in the microbiology laboratory – Meridian's target market. Along with Meridian's ILLUMIGENE product, four other companies were discussed as offering competitive products: Cepheid, BD, Nanosphere, and IQuum. Illumina was not discussed in this

comparative analysis because Illumina did not at the time (and does not now) offer a competitive product.

Pursuant to 37 C.F.R. § 2.20, the undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements and the like may jeopardize the validity of the application or document or any registration resulting therefrom, declares that all statements made of my own knowledge are true; and all statements made on information and belief are believed to be true.

Executed on February 5, 2015.



Vecheslav A. Elagin

ELAGIN EXHIBIT A

Meridian Bioscience, Inc.
Inspired Science. Trusted Solutions.®

INFORMATION

For Immediate Release
October 30, 2008
Contact: 513.271.3700
John A. Kraeutler, Chief Executive Officer

NEW MOLECULAR TEST FOR C. *difficile* FROM MERIDIAN BIOSCIENCE EXPECTED TO BE LAUNCHED IN FISCAL YEAR 2009

Meridian Bioscience, Inc., Cincinnati, Ohio (NASDAQ: VIVO) today announced, in conjunction with the Association for Molecular Pathology 2008 Annual Meeting now occurring in Grapevine, Texas, that it anticipates launching a simple, rapid new molecular test for the toxin-producing forms of the C. *difficile* bacteria in the second half of fiscal year 2009. This innovative molecular test is based upon Loop Mediated Isothermal Amplification (LAMP) licensed by Meridian Bioscience from Eiken Chemicals, Ltd. (Japan) in 2006. Clostridium difficile is most common in hospitals and, recent hypervirulent forms of the bacteria have caused increased infection and mortality. C. *difficile* is carried in the gut of 3% of healthy humans but prevalence in hospital patients tends to be much higher. Elderly people in hospitals being treated with antibiotics are most at risk of developing infection.

The new "LAMP" C. *difficile* test has been in development for two years and is now completing beta site evaluations. Meridian has successfully completed its FDA pre-submission activities and expects to initiate clinical trials in January with a 510(k) application to follow within 90-120 days thereafter. International revenues are likely in the second half of Fiscal 2009, with U.S. sales to follow FDA clearance.

This new test is based upon the amplification of DNA from toxin-producing strains of the C. *difficile* bacteria. The procedure is remarkably simple, highly sensitive, and yields results in less than one hour. It requires no expensive capital equipment. The test relies upon a simple 3-step procedure that includes extraction, amplification and detection. The entire amplification is isothermal and results are read in a simple heater/reader. All reagents and disposables will be contained in the final kit package capable of room temperature storage. Meridian believes that the "point-of-care" simplicity of this technology, along with its cost efficient design, makes this innovative methodology ideal for helping to diagnose most acute infectious diseases, especially in those instances where there is a low level of the biological target.

Jack Kraeutler, Chief Executive Officer stated, "Our development of the "LAMP" technology has progressed to a point where we have achieved our goal of simplicity, speed, affordability and broad applicability. This technology will appeal to any size acute care laboratory that is seeking molecular amplification capability with no capital investment and, the ultimate in simplicity and accuracy. We are eager to complete our clinical trials and our subsequent FDA submission. We look forward to satisfying the needs of the infectious disease labs that have reacted so positively to our market research. We believe that today's laboratories need a choice of rapid diagnostic testing methods. As we move ahead, I look forward to the expansion of the "LAMP" testing menu, as well as continuing to focus on developing rapid immunoassays, to satisfy best the needs of the acute care laboratory."

FORWARD LOOKING STATEMENTS

The Private Securities Litigation Reform Act of 1995 provides a safe harbor from civil litigation for forward-looking statements accompanied by meaningful cautionary statements. Except for historical information, this report contains forward-looking statements which may be identified by words such as "estimates", "anticipates", "projects", "plans", "seeks", "may", "will", "expects", "intends", "believes", "should" and similar expressions or the negative versions thereof and which also may be identified by their context. Such statements, whether expressed or implied, are based upon current expectations of the Company and speak only as of the date made. The Company assumes no obligation to publicly update any forward-looking statements. These statements are subject to various risks, uncertainties and other factors that could cause actual results to differ materially, including, without limitation, the following: Meridian's continued growth depends, in part, on its ability to introduce into the marketplace enhancements of existing products or new products that incorporate technological advances, meet customer requirements and respond to products developed by Meridian's competition. While Meridian has introduced a number of internally developed products, there can be no assurance that it will be successful in the future in introducing such products on a timely basis. Ongoing consolidations of reference laboratories and formation of multi-hospital alliances may cause adverse changes to pricing and distribution. Costs and difficulties in complying with laws and regulations administered by the United States Food and Drug Administration can result in unanticipated expenses and delays and interruptions to the sale of new and existing products. Changes in the relative strength or weakness of the U.S. dollar can change expected results. One of Meridian's main growth strategies is the acquisition of companies and product lines. There can be no assurance that additional acquisitions will be consummated or that, if consummated, will be successful and the acquired businesses successfully integrated into Meridian's operations. In addition to the factors described in this paragraph, Part I, Item 1A Risk Factors of our Form 10-K contains a list of uncertainties and risks that may affect the financial performance of the Company.

Meridian is a fully integrated life science company that manufactures, markets and distributes a broad range of innovative diagnostic test kits, purified reagents and related products and offers biopharmaceutical enabling technologies. Utilizing a variety of methods, these products and diagnostic tests provide accuracy, simplicity and speed in the early diagnosis and treatment of common medical conditions, such as gastrointestinal, viral and respiratory infections. Meridian's diagnostic products are used outside of the human body and require little or no special equipment. The Company's products are designed to enhance patient well-being while reducing the total outcome costs of healthcare. Meridian has strong market positions in the areas of gastrointestinal and upper respiratory infections, serology, parasitology and fungal disease diagnosis. In addition, Meridian is a supplier of rare reagents, specialty biologicals and related technologies used by biopharmaceutical companies engaged in research for new drugs and vaccines. The Company markets its products and technologies to hospitals, reference laboratories, research centers, veterinary testing centers, physician offices, diagnostics manufacturers and biotech companies in more than 60 countries around the world. The Company's shares are traded through NASDAQ's Global Select Market, symbol VIVO. Meridian's website address is www.meridianbioscience.com.

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Meridian Bioscience, Inc.
Inspired Science. Trusted Solutions.®

INFORMATION

For Immediate Release
July 13, 2010
Contact: 513.271.3700
John A. Kraeutler, Chief Executive Officer

MERIDIAN BIOSCIENCE RECEIVES FDA CLEARANCE FOR NEW *illumigene*™ MOLECULAR PLATFORM

Meridian Bioscience, Inc., Cincinnati, Ohio (NASDAQ:VIVO) today announced that it has received clearance from the U.S. Food and Drug Administration (FDA) for its new molecular amplification assay, ***illumigene***™ *C. difficile*. *Clostridium difficile* is a bacterium that can cause diarrhea and, in severe cases, a life-threatening inflammation of the colon. The ***illumigene*** molecular amplification assay detects the presence of the toxin producing region from the *C. difficile* DNA, and provides highly accurate results in under an hour. Meridian, a leading manufacturer of rapid immunoassay *C. difficile* tests, expands its existing portfolio with this new, simpler molecular assay. As a result, the Company will be uniquely positioned in the market to provide a full line of testing solutions that will meet the needs of its domestic and international customers.

The new ***illumigene*** *C. difficile* molecular diagnostic system provides high levels of sensitivity for diagnosing this serious, infectious disease. Its simple workflow requires minimal hands-on time per sample. The product has been recently launched successfully in Europe.

Jack Kraeutler, Chief Executive Officer, commented, "Some years ago, Meridian recognized that our infectious disease lab customers may require molecular amplification capabilities in specific instances. Our goal has been to deliver the power of molecular amplification in a platform that is simple, highly cost effective, and accessible for any of our lab customers. With the introduction of ***illumigene*** *C. difficile*, we have achieved the first step towards that goal. We look forward to the success of ***illumigene*** *C. difficile*, and we will be expanding the test menu for this exciting new platform."

Forward Looking Statements
The Private Securities Litigation Reform Act of 1995 provides a safe harbor from civil litigation for forward-looking statements accompanied by meaningful cautionary statements. Except for historical information, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, which may be identified by words such as "estimates", "anticipates", "projects", "plans", "seeks", "may", "will", "expects", "intends", "believes", "should" and similar expressions or the negative versions thereof and which also may be identified by their context. Such statements, whether expressed or implied, are based upon current expectations of the Company and speak only as of the date made. The Company assumes no obligation to publicly update or revise any forward-looking statements even if experience or future changes make it clear that any projected results expressed or implied therein will not be realized. These statements are subject to various risks, uncertainties and other factors that could cause actual results to differ materially, including, without limitation, the following: Meridian's continued growth depends, in part, on its ability to introduce

into the marketplace enhancements of existing products or new products that incorporate technological advances, meet customer requirements and respond to products developed by Meridian's competition. While Meridian has introduced a number of internally developed products, there can be no assurance that it will be successful in the future in introducing such products on a timely basis. Ongoing consolidations of reference laboratories and formation of multi-hospital alliances may cause adverse changes to pricing and distribution. Recessionary pressures on the economy and the markets in which our customers operate, as well as adverse trends in buying patterns from customers can change expected results. Costs and difficulties in complying with laws and regulations administered by the United States Food and Drug Administration can result in unanticipated expenses and delays and interruptions to the sale of new and existing products. Changes in the relative strength or weakness of the U.S. dollar can also change expected results. One of Meridian's main growth strategies is the acquisition of companies and product lines. There can be no assurance that additional acquisitions will be consummated or that, if consummated, will be successful and the acquired businesses successfully integrated into Meridian's operations. The Company cannot predict the possible effects of potential healthcare reform in the United States and similar initiatives in other countries on its results of operations. In addition to the factors described in this paragraph, Part I, Item 1A Risk Factors of our Form 10-K contains a list and description of uncertainties, risks and other matters that may affect the Company.

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